IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IRRIMAX CORPORATION, Plaintiff, v. NEXT SCIENCE, LLC, Defendant.	CIVIL ACTION FILE NO. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Irrimax Corporation ("Irrimax" or "Plaintiff"), by and through its undersigned counsel, files this Complaint for false advertising in violation of 15 U.S.C. § 1125(a) and common law unfair competition against Defendant Next Science, LLC ("Next Science" or "Defendant") and states as follows:

THE PARTIES

1. Plaintiff Irrimax Corporation is a corporation organized under the laws of Georgia with a place of business at 1665 Lakes Parkway, Suite 102, Lawrenceville, GA, 30043.

2. Upon information and belief, defendant Next Science, LLC operates a research and development center incorporated in the state of Florida with offices at 10550 Deerwood Park Blvd #300, Jacksonville, FL 32256.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to 15 U.S.C. § 1121, 28 U.S.C. § 1331, and 28 U.S.C. § 1367.

4. This Court has personal jurisdiction over Next Science because, on information and belief, Next Science has significant contacts with and does business in this district and purposefully directs the activities that form the basis for this action towards this judicial district. For example, on information and belief, Next Science employs sales personnel based out of this district. On information and belief, Next Science regularly transacts business in this district, including by marketing products in this district and maintaining an interactive website accessible to residents of this district. By way of further example, Next Science has partnered with physicians who practice in this district to provide testimonials relating to Next Science products. In addition, Plaintiff is located in this district and, on information and belief, Defendant's advertising, promotional materials and statements complained of herein, some of which specifically refer to Plaintiff or its products, have been distributed nationally, including in this district and/or to Georgia residents. On

information and belief, Next Science is also engaging in clinical studies in Georgia directed by physicians in Georgia.

5. Venue in this judicial district is proper under 28 U.S.C. § 1391(b) at least because a substantial part of the events or omissions giving rise to the claims at issue herein occurred in this district.

BACKGROUND

Irrimax

6. Irrimax is a pioneer and leader in wound irrigation, focused on developing and marketing innovative products directed to reducing infections, healthcare costs, and improving patient outcomes.

7. The company's flagship product, Irrisept Antimicrobial Wound Lavage, is a single-use, manual, self-contained irrigation device comprised of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% water.

8. CHG acts as a preservative to help inhibit microbial growth in the solution. The mechanical action of the Irrisept system removes particulate and debris. The unique bottle design allows users to control the delivery pressure of the solution through manual bottle compression. Irrisept has successfully completed testing for cytotoxicity, skin irritation, and sensitization/immune allergic response. Irrisept is FDA-cleared (K210536), Class II Medical Device and an unclassfied

combination product. The clearance letter is available at www.accessdata.fda.gov/cdrh_docs/pdf21/K210536.pdf, a copy of which is submitted herewith as Exhibit A. The directions for use for Irrisept are available at www.irrisept.com/irrisept/overview/directions-for-use, a copy of which is attached as Exhibit B. Both the clearance materials and the directions for Irrisept confirm that Irrisept is used to irrigate the wound such that the mechanical action effectively loosens and removes wound debris.

Defendant

9. Next Science, the U.S. affiliate of a publicly traded Australian company, is in the business of developing and marketing products that seek to reduce surgical site infections.

10. Next Science recently announced FDA clearance (K203835) to market as a medical device its "MIS solution" wound irrigation product. Next Science markets this "MIS Solution" wound irrigation product using the name XPERIENCE.

11. The FDA clearance materials note that the mechanism of action for the product is mechanical—the "[m]echanical removal of debris via hydrodynamic shear"—based on use of the product externally to debride a wound by a rinsing action. The clearance materials do not describe leaving the product in the body. In fact, unlike Irrisept, the FDA classifies the MIS Solution as a medical device only

and not a combination product that has both medical device and drug components. The clearance letter is available at www.accessdata.fda.gov/cdrh_docs/pdf20/K203835.pdf, a copy of which is submitted herewith as Exhibit C. The instructions for use for XPERIENCE confirm that the product is for "External use only," that the solution is to be suctioned throughout the procedure, and that it is to be "rinse[d] away…after irrigation" if it "contacts unintended anatomy or materials." The instructions for use are available at www.nextscience.com/wp-content/uploads/2021/05/NMS-40012-XPerience-IFU-Rev-G.pdf, a copy of which is submitted herewith as Exhibit D. Both the clearance and instructions for XPERIENCE confirm that XPERIENCE is used to irrigate the wound using mechanical action to remove wound debris. Indeed, the FDA clearance materials state: "The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganism, from wounds." *See* Exhibit C at 4.

12. Next Science and Irrimax are direct competitors, both offering products used for wound irrigation directed to surgeons and other medical professionals.

Defendant's False and Misleading Statements

13. Next Science is aggressively using false and misleading statements in advertising and promotional materials to promote its new XPERIENCE product.

14. Upon information and belief, Next Science has also employed, or in

other ways compensated, health care professionals, including doctors and scientists, who have made unsupported and/or misleading statements about the XPERIENCE product on behalf of Next Science in an effort to market and increase sales and interest in the XPERIENCE product.

15. These statements have been made for commercial purposes and constitute commercial advertising and promotion for the XPERIENCE product.

16. Examples of Next Science's false and misleading statements made in advertising and promotion for its XPERIENCE product include the following:

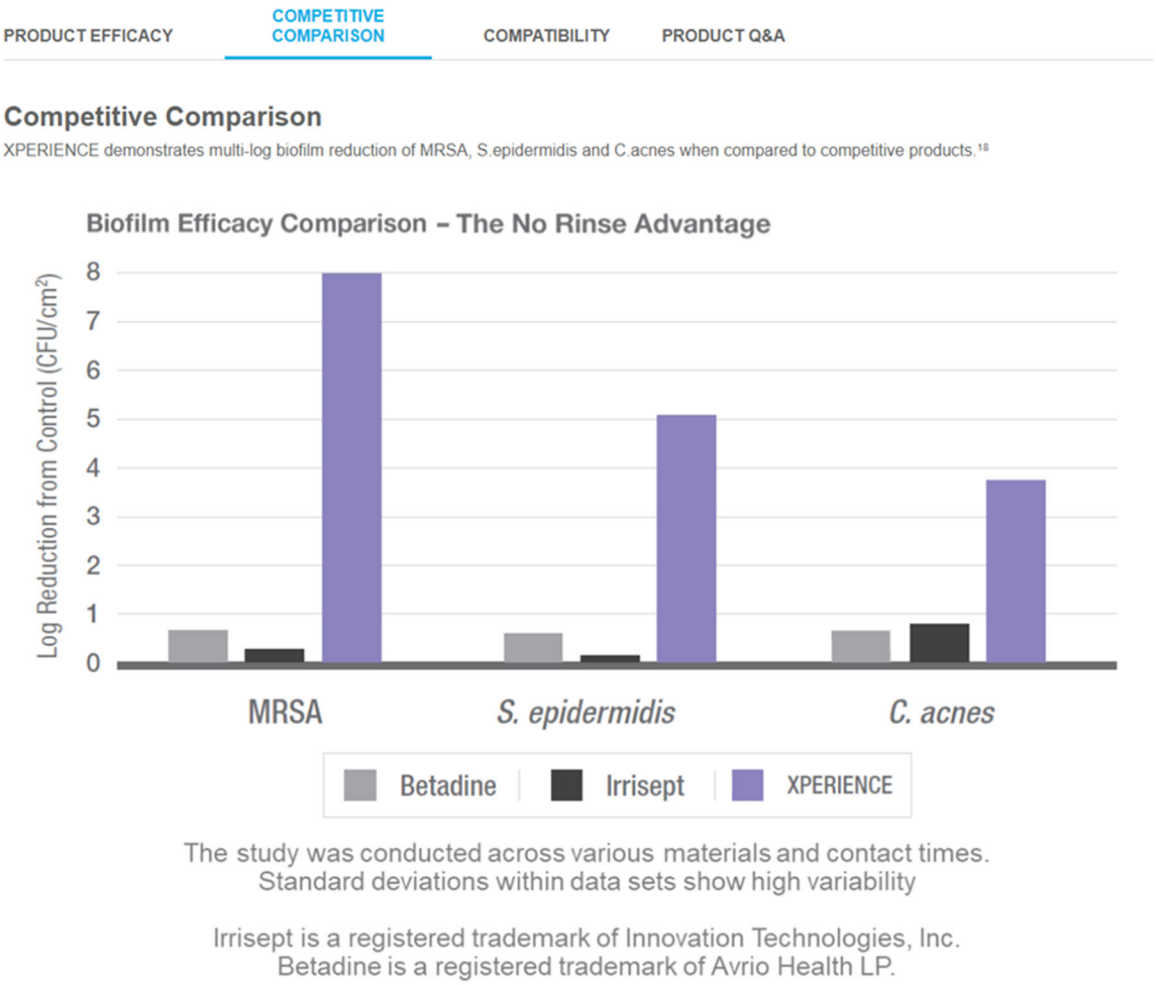
a. Next Science makes false and/or misleading comparative statements referring to Irrimax's Irrisept product, falsely claiming that tests prove Next Science's XPERIENCE product outperforms Irrisept without reliable support for such claims;

b. Next Science makes false and/or misleading statements touting that XPERIENCE is cleared by the FDA while asserting purported benefits based on chemical mechanisms of action that the FDA has not cleared for use; and

c. Next Science makes false and/or misleading statements that XPERIENCE is a "no rinse" solution that works by remaining in the body, but XPERIENCE is for external use only, must be suctioned out

during use, and may also require a rinse.

17. Next Science's website at nextscience.com has included the chart below, which on information and belief has also appeared in Next Science product brochures.

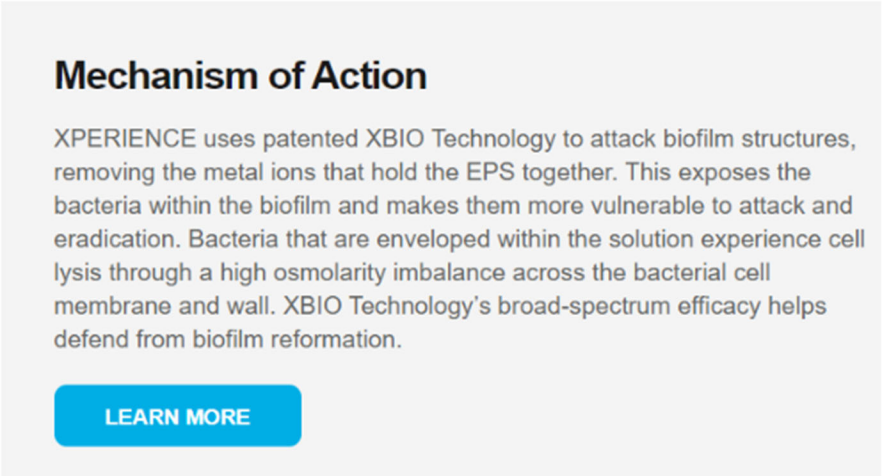


18. The chart is indicative of the types of false and/or misleading claims made by Next Science. First, the chart falsely and/or misleadingly compares apples

to oranges, with different materials and different contact times used for the different products. The chart does not disclose the materials or contact times that it used for each product. On information and belief, the contact time for XPERIENCE was significantly higher than for Irrisept. Also, on information and belief, the testing underlying the chart was not consistent with the instructions for use for Irrisept or for XPERIENCE, including because it did not account for the mechanical mechanism of action applicable to both products. And, by its own admission, there was "high variability" within the data sets.

19. Second, Next Science has repeatedly touted its XPERIENCE product as being cleared by the FDA, including by issuing two press releases in less than four months emphasizing its FDA clearance. Those press releases are attached as Exhibit E ("Next Science's XPERIENCE No Rinse Antimicrobial Solution Cleared by FDA for Sale in USA") and Exhibit F ("Clinical trial for XPERIENCE commences after receiving FDA clearance in April"). As addressed above, the FDA clearance for XPERIENCE is based on a mechanical mechanism of action. However, on information and belief, the testing referenced in the chart is based on a chemical mechanism of action. Next Science includes similar false and misleading statements on its website and in other marketing materials. For example, on its website Next Science describes the "Mechanism of Action" of XPERIENCE as

including the removal of metal ions in biofilm.



https://www.nextscience.com/xperience/

Next Science's marketing materials falsely imply that its product was cleared by the FDA based on these chemical mechanisms of action when that is not the case.

20. Third, in the chart and in other marketing materials, Next Science refers to XPERIENCE as having a "No Rinse Advantage" when, in fact, the instructions for use for XPERIENCE state that it must be suctioned out during use and may require a rinse. In other marketing materials, Next Science further claims that XPERIENCE continues to help defend against infection after closure of the wound despite instructions stating that it is for external use only. *Compare e.g.*, Exhibit E ("the residual solution remains in the surgical site after closure and continues to help defend against pathogens for several hours") and XPERIENCE Mechanism of Action video at www.nextscience.com/xperience ("XPERIENCE continues to help

defend against infections after closure") with Exhibit D ("External use only"). Again, the FDA clearance touted by Next Science refers only to mechanical removal of debris, not a product that remains in the body. And, the testing underlying Next Science's claims is unreliable (as addressed above) and does not support the broad "Advantage" over Irrisept claimed by Next Science.

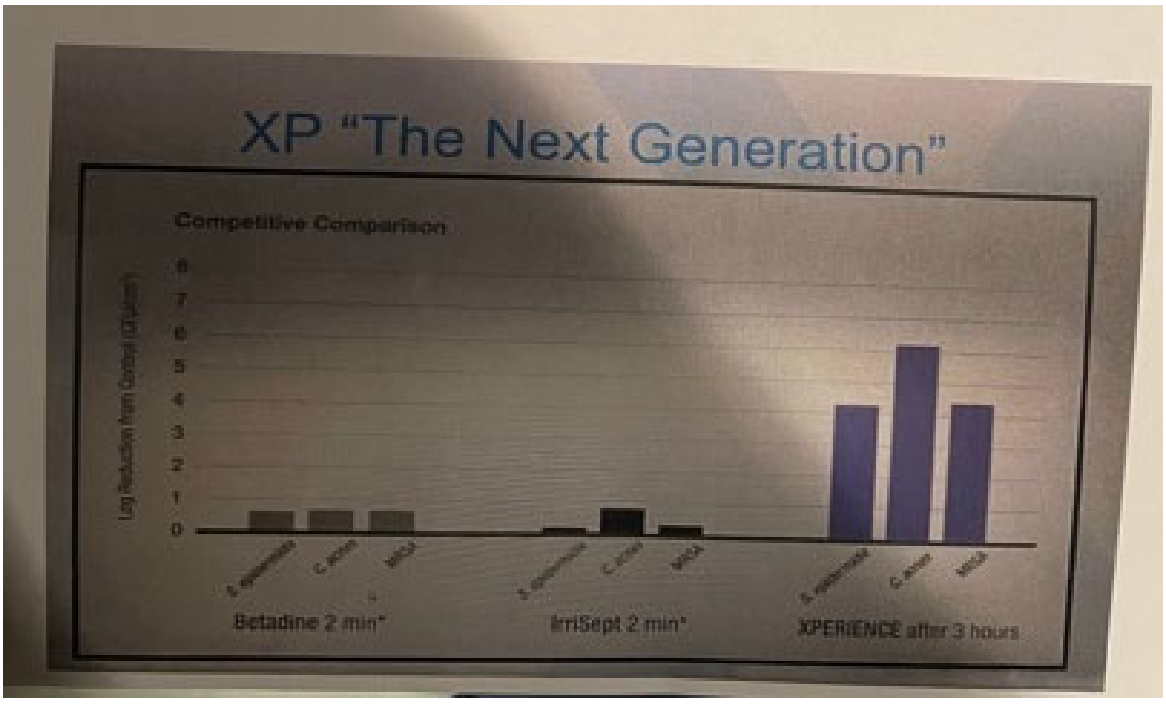
21. Irrimax promptly notified Next Science of the falsity of these statements and explained on multiple occasions and in detail the support for Irrimax's position, including that the chart was based on a study using conditions different than those under which the products are cleared for use. Next Science said that it would amend the description under the chart to note some of the limits of the study, *e.g.*, that it was in-vitro, that various materials and contact times were used, and that the solutions were applied under static conditions. The amended description stated as follows:

> This in-vitro study was conducted by an independent laboratory using various materials and contact times on biofilms grown as described in ASTM E2647 (media and incubation conditions adjusted as required for various microbial species). Solutions were applied under static conditions.

22. But the amended description does not save the chart from being false and/or misleading. Rather, it confirms that Next Science's testing is not consistent with the instructions for use or clearance for XPERIENCE or Irrisept.

23. Moreover, it recently came to Irrimax's attention that Next Science has persisted in using versions of the above chart, as well as similar charts, that do not even include the amended description that it said it would include.

24. For example, Next Science continues to distribute a sales sheet for XPERIENCE to surgeons with a similar false and misleading chart, purporting to compare the products but showing the alleged effects of Irrisept at 2 minutes as compared to XPERIENCE after 3 hours. Upon information and belief, the chart below was distributed by Next Science on or around August 9, 2021.



25. As a further example, Next Science sponsored a presentation at the Surgical Infection Society (SIS Presentation) meeting in Denver, Colorado on Monday, August 2, 2021. This presentation was promoted by Next Science on social

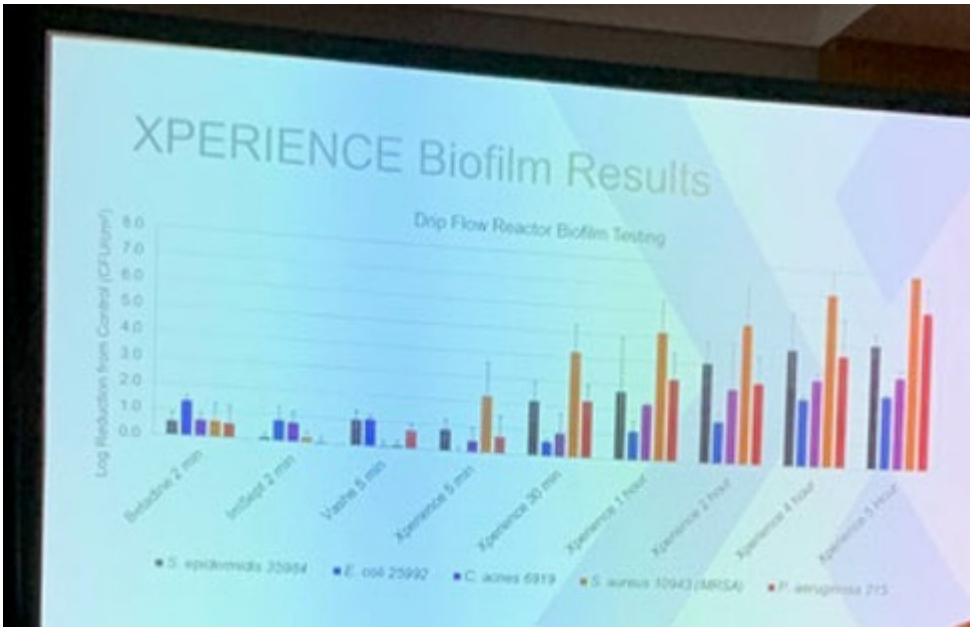
media channels as follows:

26. The Next Science sponsored presentation at SIS was given by Next Science's Medical Science Liaison Manager. The SIS presentation by Next Science continued to include the false and/or misleading statements previously challenged by Irrimax.

27. For example, slides titled "Mechanism of Action: Destroys pathogens within the solution" and "Mechanism of Action: Defends against recolonization" represent a *chemical* mechanism of action that kills bacteria and prevents reconstitution. Again, the FDA clearance for Next Science's XPERIENCE

product—which it regularly touts—is limited to its mechanical, not chemical, mechanism of action: "The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of debris, including microorganisms, from wounds." *See* Exhibit C at 4.

28. In addition, a slide titled "XPERIENCE Biofilm Results" continues to make the same type of unsubstantiated false and/or misleading superiority claims against Irrimax's Irrisept product as referenced in the chart above. The slide again purports to compare the impact of Irrimax's Irrisept product at 2 minutes versus the Next Science XPERIENCE product at 5 hours, without any qualifying limitations and again ignoring the instructions for use and FDA clearances of the products.



29. During the presentation, Next Science's employee claimed that Next

Science's XPERIENCE product operated more effectively than Irrimax's Irrisept product (referred to on the slide as "Irrisept" and in the talk as "a chlorhexidine wash") as follows:

> "With five minutes exposure [of XPERIENCE], you are getting 10 to the 6 elimination of the vast majority of bacteria and even 10 to the 3 of fungal species. When you look at biofilm elimination, which of course is the more interesting question, we get very good elimination partly because of that persistence. Right, your betadines, your chlorhexidine washes [like Irrisept], your hypochlorous acid washes … all those products, they have to be rinsed away and so they are only going to eliminate maybe 10 to the 2, 10 to the 3 fold of your bacteria and your biofilm. If you are looking at 99.9% of Staphylococcus which we're definitely trying for Staphylococcus, basically a few hours later [with Irrisept and other non-XPERIENCE options] you completely restored the [bacteria] population, it [the Irrisept product and other non-XPERIENCE options] didn't really help. In contrast, when you get a 5 hour persistence with the [XPERIENCE] product, you are going to continue to inhibit microbial regrowth in that wound site."

30. Irrimax conferred with Next Science on a number of occasions to express its concerns regarding Next Science's use of false and misleading

statements, including multiple phone calls and letters. However, on information and belief, the false and misleading statements have continued to be made, and will continue to be made in the absence of court intervention.

31. Upon information and belief, these claims by Next Science relate to the inherent qualities of the Next Science and Irrimax products, are material to the purchasing decisions of those who buy and utilize the products at issue, have a tendency to deceive and/or have deceived the relevant purchasing public, and will cause or have caused harm to Irrimax.

COUNT I
FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125(a))

32. Irrimax repeats, realleges and incorporates by reference Paragraphs 1 through 31, inclusive, as if fully set forth in this paragraph.

33. Defendant's false, deceptive, and misleading advertising in interstate commerce violates Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

34. Defendant's advertising claims regarding the XPERIENCE product are false, deceptive, and misleading.

35. Defendant's false, deceptive, and misleading claims were included in their commercial advertising and/or promotional materials.

36. Next Science has distributed their false, deceptive, and misleading

advertising claims in interstate commerce.

37. Defendant's false, deceptive, and misleading advertising claims have the capacity to deceive healthcare professionals, patients, and investors and are material to purchasing decisions.

38. Irrimax has been injured as a result of Defendant's false, deceptive, and misleading advertising.

39. Irrimax will continue to be irreparably injured unless and until Defendant's conduct is preliminarily, and thereafter, permanently enjoined by this Court, and Irrimax has no adequate remedy at law.

40. As a direct and proximate result of Defendant's false, deceptive, and misleading advertising, Irrimax has suffered harm and damages in an amount to be determined by the trier of fact.

41. Next Science has engaged in intentional and willful violation of the Lanham Act entitling Irrimax to enhanced damages and attorneys' fees and costs.

COUNT II
COMMON LAW UNFAIR COMPETITION

42. Irrimax repeats, realleges and incorporates by reference Paragraph 1 through 31, inclusive, as if fully set forth in this paragraph.

43. Defendant's false and/or misleading statements in commercial advertisements, presentations and promotional materials, constitute unfair

competition under the common law of Georgia and other states.

44. Irrimax has been and is likely to continue to be damaged as a result of Defendant's unfair competition. Defendant's actions are causing and will cause Irrimax damages in amounts presently unknown but to be determined at trial. Moreover, unless enjoined by this Court, Next Science will continue the foregoing unfair competition, causing Irrimax immediate and irreparable damage.

PRAYER FOR RELIEF

WHEREFORE, Irrimax requests entry of judgment in its favor and against Next Science as follows:

A. For judgment in favor of Irrimax and against Next Science on all of Irrimax's claims, including that Next Science has engaged in false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) and have engaged in unfair competition under common law;

B. For a preliminary and permanent injunction prohibiting Next Science and its officers, agents and servants, employees, attorneys, and all others in active concert of participation with them, pursuant to Rule 65 of the Federal Rules of Civil Procedure and 15 U.S.C. § 1116(a), from the following:

1. making false or misleading statements that XPERIENCE is superior to Irrisept based on unreliable studies;
2. making false or misleading statements that XPERIENCE is cleared by the FDA for mechanisms of action that are not the basis for its clearance;
3. making false or misleading statements that XPERIENCE is a "no rinse" solution; and
4. from otherwise unfairly competing with Irrimax;

C. For an award to Irrimax of the damages it has incurred, and/or profits obtained by Next Science, as a result of Defendant's false advertising, in an amount to be determined by the trier of fact;

D. For enhanced damages and/or profits awarded to Irrimax pursuant to 15 U.S.C. § 1117(a) and other applicable law according to proof at trial;

E. For corrective advertising damages and/or an order requiring Next Science to engage in corrective advertising;

F. For Irrimax's reasonable attorneys' fees, costs, expenses, and interest pursuant to 15 U.S.C. § 1117(a) and other applicable law; and

G. For such other and further relief as this Court may deem just and appropriate.

DEMAND FOR JURY TRIAL

Irrimax demands trial by jury of all issues so triable.

DATED: August 23, 2021

Respectfully submitted,

KING & SPALDING LLP

s/ *Russell E. Blythe*

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